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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,857	08/14/2003	Scott Koenig	505 421 999 009	1191

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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,857	KOENIG ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-107 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-107 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

2. Claims 1-107 are pending.

3. Claim 80 recites a "vaccine composition". The specification discloses that such "vaccine composition" includes antigen-specific vaccines, anti-idiotypic vaccines, dendritic cell vaccines or DNA vaccines (see pages 120-121 of the specification as-filed). These lists of "vaccine composition" are structurally distinct.

Therefore, if applicant elects any groups that recite "vaccine composition", then a restriction for this would be set forth for each "vaccine composition" as separate group, irrespective of the format of the claims. Upon election of claim 80, Applicant is requested to amend the claim to set forth the elected inventive group.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, 23, 27-32, 34, 36-43, 81-90, 104-107, drawn to an antibody or fragment thereof that binds FcγRIIB with greater affinity than human native FcγRIIA, classified in Class 530, subclass 387.9.

II. Claims 22, 24-26, drawn to a bispecific antibody comprising a first heavy chain-light chain pair that specifically binds FcγRIIB, and a second heavy chain-light chain pair that specifically recognizes a tumor antigen, classified in Class 530, subclass 387.3.

It is noted that claim 24 recites "a heterologous polypeptide" and dependent claim 25 recites "wherein said heterologous polypeptide is an antibody". Therefore for restriction purposes, claim 24 reads as a "bispecific antibody".

III. Claims 33, 35, and 91-92, drawn to a method of producing a monoclonal antibody specific for FcγRIIB by immunizing FcγRIIA transgenic mice with purified FcγRIIB, classified in Class 436, subclass 547.

IV. Claims 44-50, drawn to an isolated nucleic acid comprising a nucleotide sequence encoding a heavy chain or a light chain of the antibody or fragment, vectors, host cells and the method of producing the antibody or fragment thereof that binds FcγRIIB with greater affinity than human native FcγRIIA recombinantly, classified in Class 435, subclass 69.6; Class 536, subclass 23.5; Class 435 subclasses 252.3, and 320.1.

V. Claims 51-59, 93-103, drawn to a method of treating cancer comprising administering a first antibody or fragment that specifically binds FcγRIIB, and a second cytotoxic antibody that specifically binds cancer antigen, classified in Class 424, subclass 133.1.

VI. Claims 60-64, drawn to a pharmaceutical composition comprising a antibody or fragment thereof that specifically binds FcγRIIB, a cytotoxic antibody and a carrier, classified in Class 424, subclass 130.1.

VII. Claims 65-72, drawn to a method of treating autoimmune disorder comprising administering an antibody or fragment, classified in Class 424, subclass 130.1.

VIII. Claims 73-76, drawn to a method of treating or preventing an IgE-mediated allergic disorder with an antibody or fragment thereof that binds FcγRIIB with greater affinity than human native FcγRIIA, classified in Class 424, subclass 130.1.

IX. Claims 77 and 80, drawn to a method of enhancing cytotoxic effect or immune response using an antibody or fragment thereof that binds FcγRIIB with greater affinity than human native FcγRIIA, classified in Class 424, subclass 130.1.

X. Claims 78 and 79, drawn to a method of diagnosis of an autoimmune disease with an antibody or fragment thereof that binds FcγRIIB with greater affinity than human native FcγRIIA, classified in Class 435, subclass 7.1.

5. Groups I, II, IV, and VI are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, antibody, bispecific antibody, nucleic acid, vector, host cells, and the pharmaceutical composition comprising different antibodies are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each product is patentably distinct, and searching of these Inventions would impose an undue burden.

6. Groups (III and IV) and (I, II, and VI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case, the product, antibody in Groups I, II, and VI can be made using an amino acid synthesizer or antibody phage libraries in addition to the recombinant or transgenic methods recited.

7. Groups (I, II, and VI) and (V and VII-X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case, the product antibody in Groups I, II, and VI can be used for affinity purification or immunodetection, in addition to methods of treating, diagnosis or enhancing cytotoxic effect.

8. Groups IV, V, VII-X are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, the method of making antibody, the method of treating, diagnosing, and enhancing cytotoxic effect differ with respect to one or more of ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Furthermore, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

9. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

10. This application contains claims directed to the following patentably distinct species of the claimed inventions:

11. If any one of the Groups I and V-IX is elected, applicant is further required to elect an antibody or fragment thereof wherein the antibody is produced by one specific clone (e.g. clone 2B6 having ATCC accession number PTA-4591 as recited in claim 36) and wherein the antibody is:

A) NOT conjugated, **OR**

B) conjugated to one specific cytotoxin (e.g. paclitaxel as recited in claim 29).

These species are distinct because antibody conjugated with different cytotoxins differ in structures, physicochemical properties and mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility.

Applicant is required under 35 USC 121 to elect a single disclosed species of an antibody to which the claims would be restricted if no generic claim is finally held to be allowable.

12. In addition, if any one of the Groups I and V-IX is elected, applicant is further required to elect an antibody or fragment thereof wherein the antibody is produced by one specific clone (e.g. clone 2B6 having ATCC accession number PTA-4591 as recited in claim 36) and wherein the antibody:

i) does NOT comprise modification in the Fc region, **OR**

ii) comprises modification in specific amino acid positions in the Fc region (e.g. position 241 as disclosed on page 47 of the instant specification).

These species are distinct because antibodies with modification in different amino acid positions differ in structures, physicochemical properties and mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility.

Applicant is required under 35 USC 121 to elect a single disclosed species of an antibody to which the claims would be restricted if no generic claim is finally held to be allowable.

13. In addition to all of the species elections above, if any one of the Groups I and V-IX is elected, applicant is further required to elect an antibody or fragment thereof wherein the antibody:

a) agonizes at least one activity of FcγRIIB, **OR**

b) antagonized at least one activity of FcγRIIB.

These species are distinct because the agonizing and antagonizing antibodies are mutually exclusive in that they reach opposing endpoints.

Applicant is required under 35 USC 121 to elect a single disclosed species of an antibody to which the claims would be restricted if no generic claim is finally held to be allowable.

14. If Group II is elected, applicant is further required to elect one bispecific antibody comprising a first heavy chain-light chain pair that specifically binds FcγRIIB, and a second heavy chain-light chain that specifically binds to one specific tumor antigen.

Claims 22 and 24-26 also recites a "tumor antigen". The specification discloses on pages 93-94 long lists of such "tumor antigen" includes KS ¼ pan-carcinoma antigen. These tumor antigens are structurally distinct; thus bispcific antibodies with a second heavy chain-light chain that specifically binds to the tumor antigens are distinct.

Applicant is required under 35 USC 121 to elect a single disclosed species of an antibody to which the claims would be restricted if no generic claim is finally held to be allowable.

15. In addition, if Group V is elected, applicant is further required to elect a method:

A) without additional therapy, **OR**

B) with one specific additional cancer therapies (e.g. chemotherapy as recited in claim 57).

These species are distinct because methods of treating cancer differ with respect to one or more of ingredients, method steps and/or endpoints.

Applicant is required under 35 USC 121 to elect a single disclosed species of a method of treating cancer to which the claims would be restricted if no generic claim is finally held to be allowable.

In addition, applicant is required to elect a method of treating with:

i) one specific second antibody (e.g. Herceptoin® as recited in claim 53), **AND**

ii) one particular cancer (e.g. breast cancer: medullary breast cancer as recited in claim 52 and disclosed on page 90 of the instant specification)

These species are distinct because methods of treating cancer differ with respect to one or more of ingredients, method steps and/or endpoints.

Applicant is required under 35 USC 121 to elect a single disclosed species of a method of treating cancer to which the claims would be restricted if no generic claim is finally held to be allowable.

16. If Group VI is elected, applicant is further required to elect a method of treating one specific autoimmune disorder (e.g. alopecia areata as disclosed on pages 99-100 of the instant specification) by administering an antibody

A) without further administering other agents,

B) with further administering one or more specific anti-inflammatory agents (e.g. aspirin as recited in claim 72), **OR**

C) with further administering one or more specific immunomodulatory agent (e.g. methotrexate as recited in claim 70).

These species are distinct because methods of treating different autoimmune disorders differ with respect to one or more of ingredients, method steps and/or endpoints.

Applicant is required under 35 USC 121 to elect a single disclosed species of a method of treating an autoimmune disorder to which the claims would be restricted if no generic claim is finally held to be allowable.

17. If Group VII is elected, applicant is further required to elect a method of treating or preventing one specific Ig-E-mediated allergic disorder (e.g. asthma as recited in claim 74).

These species are distinct because methods of treating different Ig-E-mediated allergic disorders differ with respect to one or more of ingredients, method steps and/or endpoints.

Applicant is required under 35 USC 121 to elect a single disclosed species of a method of treating an Ig-E-mediated allergic disorder to which the claims would be restricted if no generic claim is finally held to be allowable.

18. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

19. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

20. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

21. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
August 18, 2006

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TC 1600
8/18/06